



Qbal[®] 500mcg Tablets/Injection



(Mecobalamin)

Description:

QBAL (Mecobalamin) is a B12 containing coenzyme with an active methyl base. It plays an important role in red blood cell formation, methylation reaction, brain and nervous system functions and immune system functions. Chemically, mecobalamin is described as α (5,6-Dimethylbenzimidazolyl)-Co-methyl-co-bamide. The molecular formula is $C_{63}H_{91}CoN_{13}O_{14}P$.

Composition:

Qbal 500mcg Tablets:

Each tablet contains: Mecobalamin J.P. 500 mcg
(Product Specs.: J.P.)

Product Contains Lactose

Qbal 500mcg Injection:

Each ampoule contains: Mecobalamin J.P. 500 mcg
(Product Specs.: Bosch)

Clinical Pharmacology:

Pharmacodynamic Properties:

- *Mecobalamin is a kind of endogenous coenzyme B12 :*

As a coenzyme of methionine synthetase, mecobalamin plays an important role in transmethylation in the synthesis of methionine from homocysteine.

- *Mecobalamin is well transported to nerve cell organelles, and promotes nucleic acid and protein synthesis :*

Mecobalamin is better transported to nerve cell organelles than cyanocobalamin and promotes nucleic acid and protein synthesis more than cobamide does. Experiments with cells from the brain origin and spinal nerve cells also show mecobalamin to be involved in the synthesis of thymidine from deoxyuridine, promotion of deposited folic acid utilization and metabolism of nucleic acid.

- *Mecobalamin promotes axonal transport and axonal regeneration :*
Mecobalamin normalizes axonal skeletal protein transport in sciatic nerve cells. Mecobalamin exhibits neuropathologically and electrophysiologically inhibitory effects on nerve degeneration in neuropathies induced by drugs, such as adriamycin, acrylamide, and vincristine.

- *Mecobalamin promotes myelination (phospholipid synthesis) :*
Mecobalamin promotes the synthesis of lecithin which is the main constituent of medullary sheath lipid. It also increases myelination of neurons in rat tissue culture more than cobamide does.

- *Mecobalamin restores delayed synaptic transmission and diminished neurotransmitters back to normal :*

Mecobalamin restores end-plate potential induction early by increasing nerve fiber excitability in the crushed sciatic nerve. In addition, mecobalamin normalizes diminished levels of acetylcholine in brain tissue of choline-deficient diet.

- *Mecobalamin promotes the maturation and division of erythroblasts, thereby*

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(میکوبالامین)

alleviating anaemia :

Vitamin B12-deficiency may cause specific megaloblastic anaemia. Mecobalamin promotes nucleic acid synthesis in bone marrow and the maturation and division of erythroblasts, thereby increasing erythrocyte production.

Pharmacokinetic Properties

Absorption

Vitamin B12 substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically.

Distribution

Vitamin B12 is extensively bound to specific plasma proteins called transcobalamin₁, transcobalamin₂ and appears to be involved in the rapid transport of the cobalamins to tissues. Vitamin B12 is stored in the liver. Vitamin B12 diffuses across the placenta and also appears in breast milk.

Elimination

Vitamin B12 is excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means.

40-80% of the cumulative amount of total B12 excreted in the urine by 24 hrs after single-dose administration was excreted within the first 8 hrs.

Therapeutic Indications:

Qbal (Mecobalamin) is indicated for the treatment of:

- Peripheral neuropathies.
- Megaloblastic anemia caused by vitamin B12 deficiency.

Dosage and Administration:

Peripheral Neuropathies

Tablets

The usual adult dosage for oral use is 3 tablets (1,500 µg of mecobalamin) daily divided into three doses. The dosage may be adjusted depending on the patient's age and symptoms.

Injection

The usual dosage for adults is 1 ampoule (500mcg of mecobalamin) a day administered intramuscularly or intravenously three times a week.

Megaloblastic anemia

The usual dosage for adults is 1 ampoule (500mcg of mecobalamin) a day administered intramuscularly or intravenously three times a week. After approximately 2 months of medication, the dose should be reduced to a single administration of 1 ampoule at 1 to 3 months intervals for maintenance therapy.

Method of Administration:

The cut point of the ampoule should be wiped with alcohol swab before opening. In intramuscular administration, care should be exercised to avoid adverse effects on tissues or nerves. Repeated injections at the same site should be avoided. Do not inject at innervated site. In case of severe pain after insertion of injection or if blood flows back into the syringe, withdraw the needle immediately and inject at a different site.

Contraindications:

Hypersensitivity to mecobalamin or other vitamin B12 containing products.

Warnings and Precautions:

This product should not be used aimlessly for more than one month unless it is effective. Vitamin B12 should, if possible, not be given to patients with suspected vitamin B12 deficiency without first confirming the diagnosis. Where it is desirable to start therapy immediately, combined treatment for both deficiencies may be started once suitable samples have been taken to permit diagnosis of the deficiency, and the patient converted to the appropriate treatment once the cause of the anemia is known. Regular monitoring of the blood is advisable.

Although the haematological symptoms of B12 deficiency and folate deficiency are similar, it is important to distinguish between them since the use of folate alone in B12-deficient megaloblastic anaemia can improve haematological symptoms without preventing aggravation of accompanying neurological symptoms, and may lead to severe nervous system sequelae such as subacute combined degeneration of the spinal cord. Use of doses greater than 10 micrograms daily may produce a haematological response in patients with folate deficiency and indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B12 deficiency.

Mecobalamin is susceptible to photolysis. Light decreases the content of mecobalamin and tablets may change colour (eg. turn reddish) with exposure to moisture. Therefore, this product should be used promptly after the package is opened, and caution should be taken so as not to expose the tablets/capsules to light and moisture.

The prolonged use of larger doses of mecobalamin is not recommended for patients whose occupation requires the handling of mercury or mercury compounds.

Drug Interactions:

Absorption of vitamin B12 from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists and colchicine. Serum concentrations may be decreased by concurrent administration of oral contraceptives. Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations. Parenteral chloramphenicol may attenuate the effect of vitamin in B12 in anemia.

Adverse Effects:

Dermatologic effects:

Rash ; In the event of such symptoms, treatment should be discontinued.

Gastrointestinal Effects:

Anorexia, nausea/vomiting and diarrhea

Neurologic Effects (Central nervous system):

Headache

Others:

- Anaphylactoid reaction : decrease in blood pressure or dyspnea, may occur.
- Patients should be carefully observed. In the event of such symptoms, treatment should be discontinued immediately and appropriate measures taken.
- Hot sensation
- Diaphoresis
- Pain/induration at the site of intramuscular injection

Use in Pregnancy and Lactation:

Pregnancy:

There are no data available for mecobalamin to be used in pregnant women Therefore Mecobalamin should only be used during pregnancy under physician supervision.

Lactation:

There are no data available for mecobalamin to be used in lactating women. Thus It is not recommended.

Expire Date:

Tablets 3 Years
Injection 2 Years

INSTRUCTIONS:

- Protect from light, heat & moisture store below 30°C.
- Keep out of the reach of children.
- The expiration date refer to the product correctly stored at the required condition.
- Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
- To be sold on prescription of a registered medical practitioner only.

PRESENTATION

Qbal 500mcg Tablets: Cold Form & Cold Seal Alu Alu pack of 30's tablets.
Qbal 500mcg Injection: Pack of 1x50 ampoules.

ہدایات:

روشنی، نمی اور گرمی سے محفوظ رکھیں۔ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔



Manufactured by:

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